

## **REMARKS**

After entry of this paper, claims 2, 4, 8, 10-15, 18, 22, 27, 30, 34, 36 and 47-51 will be pending. Claims 2, 27 and 48 have been amended to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, these amended claims recite that the cancer is associated with an aberrant expression and/or activity of ErbB-1. Support for this claim amendment can be found in the originally-filed application at, *e.g.*, page 3, lines 21-27. No new matter has been added.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

### **I. Information Disclosure Statement**

The Examiner states that several citations in the Information Disclosure Statement received on February 5, 2008 [sic, 2007] lack a publication date. The dates for these citations are provided in the Supplemental Information Disclosure Statement submitted herewith.

### **II. Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

In the Office Action, the Examiner rejects claims 2, 4, 8, 10-15, 18, 27 and 48 under 35 U.S.C. § 112, second paragraph. In particular, the Examiner contends that it is not clear if claims 2, 27 and 48 limit the therapy or chemotherapy to a regimen that targets ErbB-1 in particular, or if the phrase “a radiotherapy or a chemotherapy regimen for a ErbB-1 positive tumor” or “a therapy regimen for a ErbB-1 positive tumor” refers to a chemotherapy that is standard for a particular type of cancer, where that particular type of cancer happens to be one that usually expresses ErbB-1. Claims 2, 27 and 48 have been amended herein to recite that the cancer is associated with an aberrant expression and/or activity of ErbB-1. It is believed that the amended claims comply with the requirements of 35 U.S.C. § 112, second paragraph, and, respectfully, the rejection should therefore be withdrawn.

### **III. Claim Rejections Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejects claims 2, 4, 8, 10, 12, 13, 15, 22, 30, 34, 36 and 47-51 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,968,603 to Slamon (“Slamon”). The Examiner also rejects these claims under 35 U.S.C. § 102(b) as

allegedly being anticipated by U.S. Patent No. 5,994,701 [sic, 5,994,071] to Ross ("Ross"). For the following reasons, Applicant disagrees.

Claim 2 recites a method for determining the prognosis of a cancer in a subject. Claims 22 and 47 both recite a method for improving the effectiveness of cancer treatment in a subject. In each of these claims, a sample is obtained from the subject during a period of remission. Neither Slamon nor Ross teaches that the sample is obtained *during a period of remission*. In addition, claim 2 further recites that the subject has been previously treated with a radiotherapy or a chemotherapy regimen. Neither cited reference discloses this claim limitation. In fact, in Slamon, the tissue sample is obtained from the surgically removed tumor in the case of solid tumors (col. 3, lines 16-17). Ross similarly teaches that the sample is prepared from surgically removed tissue (col. 5, lines 40-41).

As such, Applicant respectfully submits that claims 2, 22, 47 and their respective dependent claims are neither taught nor suggested by either Slamon or Ross, and requests that the rejections under 35 U.S.C. § 102 be withdrawn.

#### **IV. Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejects claims 2, 4, 8, 10-13, 15, 22, 30, 34, 36 and 47-51 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Slamon and further in view of DiGiovanna *et al.*, "Activation State-specific Monoclonal Antibody Detects Tyrosine Phosphorylated p185<sup>neu/erbB-2</sup> in a Subset of Human Breast Tumors Overexpressing This Receptor", *Cancer Research*, 55:1946-55, 1995 ("DiGiovanna"). Specifically, the Examiner acknowledges that Slamon does not teach detection of ErbB-2 receptor related activity, *e.g.*, phosphorylation, but contends that DiGiovanna supplies this teaching. The Examiner also rejects claims 2, 4, 8, 10, 12, 14, 22, 30, 34, 36 and 47-51 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Slamon and further in view of U.S. Patent No. 6,387,638 to Ballinger ("Ballinger"). Specifically, the Examiner acknowledges that Slamon fails to teach or suggest the use of an ErbB receptor ligand as an ErbB receptor probe, but contends that Ballinger provides this teaching. For the following reasons, Applicant respectfully disagrees.

As discussed above, Slamon fails to teach or suggest that the sample is obtained from a subject *during a period of remission*, as recited in claims 2, 22 and 47. DiGiovanna and

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Reply dated December 15, 2009  
In Rsp to Office Action dated July 16, 2009

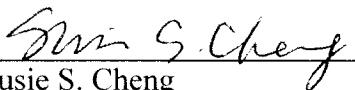
Ballinger do not cure this deficiency. Specifically, these two references fail to teach or suggest the very limitation missing from Slamon, *i.e.*, that the sample is obtained during a period of remission.

As such, Applicant respectfully submits that claims 2, 22, 47 and their respective dependent claims are patentable over Slamon in view of DiGiovanna or Ballinger, and requests that the rejections under 35 U.S.C. § 103 be withdrawn.

Applicant respectfully requests that the above remarks be entered and made of record in the file history of the instant application. No additional fee is believed to be due in connection with this submission. In the event that a fee is required, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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